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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/782,245

02/18/2004

Jaime Romero

OS 457.002

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EXAMINER
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AHMED, HASAN SYED

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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08/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/782,245	<b>Applicant(s)</b> ROMERO	
	<b>Examiner</b> Hasan S. Ahmed	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-47 and 49-69 is/are pending in the application.
- 4a) Of the above claim(s) 1-22, 26, 30, 46, 49, 50 and 52-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-25, 27-29, 31-45, 47, 51, 68 and 69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

- Receipt is acknowledged of applicant's amendment and remarks, which were filed on 14 June 2007.
- The 35 USC 112 rejection of the previous Office action is withdrawn in view of the amendment.
- Applicant's arguments have been considered but are moot in view of the new grounds of rejection.

\* \* \* \* \*

### ***Election/Restrictions***

In view of applicant's remarks, claims 27-29, 31-45, 47, 51, 68 and 69 are hereby entered, as they depend from independent claim 23

Claims 1-22, 26, 30, 46, 49-50, and 52-67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions.

\* \* \* \* \*

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27 and 28 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 27 and 28 recite the limitations "core" and "semipermeable coating". There is insufficient antecedent basis for this limitation in the claim in independent claim 23.

\* \* \* \* \*

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-25, 27-29, 31-45, 47, 51, 68 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skinner (U.S. Patent No. 6,210,710) in view of Miller (U.S. Application No. 20050008690), further in view of Cristofori et al. (U.S. Patent No. 5,252,339).

Skinner teaches a timed (sustained) release nutritional supplement (see col. 2, lines 8-22). The disclosed composition is comprised of:

- the water-soluble nutritional supplement (ascorbic acid) of instant claims 23-25 (see col. 3, line 58);
  - the saccharide (lactose) of instant claims 23-25 and 32-35 (see col. 4, line 49);
  - the excipient (calcium phosphate) of instant claims 23-25 (see col. 4, lines 48-49);
  - the lubricant (magnesium stearate) of instant claims 23-25 (see col. 4, line 59);
  - the agglutinative (hydroxyethylcellulose) of instant claims 23-25 (see col. 2, line 66);
- and

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- the plasticizer (stearic acid) of instant claims 23-25 (see col. 4, line 58);
- the core and coating of instant claim 28 (see col. 5, lines 9-26);

Skinner explains that the disclosed composition is beneficial because it provides flexibility in release profiles that are stable and economical for compressed tablets (see col. 1, lines 48-56).

While Skinner does not explicitly teach all the instant claimed percentages, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

Skinner teaches that release profiles may be adjusted as desired (see col. 5, lines 15-26). Thus, the release profile of instant claims 23 and 51 may be determined by a person of ordinary skill in the art based on routine experimentation.

Skinner does not disclose the capsule of instant claim 29, the silicon dioxide of instant claim 37, the talc of instant claim 39, the HPMC of instant claim 41, the Shellac

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of instant claim 43, the chondroitin of instant claim 47, or the glucosamine sulfate of instant claim 68.

Miller teaches a capsule formulation (see abstract) comprising:

- the silicon dioxide of instant claim 37 (see example 13);
- the talc of instant claim 39 (see paragraph 0090);
- the HPMC of instant claim 41 (see paragraph 0060);
- the Shellac of instant claim 43 (see example 13);
- the chondroitin of instant claim 47 (see example 1); and
- the glucosamine sulfate of instant claim 68 (see example 1).

Skinner does not disclose the diethylphthalate of instant claim 45. However, use of diethylphthalate as a plasticizer is well known in the art, as shown by Cristofori (see col. 5, line 2).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose water-soluble nutritional supplement in a timed release formulation comprising a saccharide, an excipient, a lubricant, an agglutinative, and a plasticizer, as taught by Skinner. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it provides flexibility in release profiles that are stable and economical for compressed tablets, as explained by Skinner.

\* \* \* \* \*

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23-25, 27-29, 31-45, 47, 51, 68 and 69 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-59 of copending Application No. 10/910,787 ('787). Although the conflicting claims are not identical, they are not patentably distinct from each other because '787 claims a timed release composition comprising a saccharide, an excipient, a lubricant, an agglutivative, and a plasticizer. See claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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HUMERA N. SHEIKH  
PRIMARY EXAMINER